

# marketinsight

REPORT

## CONTROL & IT

**Early adopters are setting the stage for pharma's widespread use of continuous manufacturing and advanced control.**

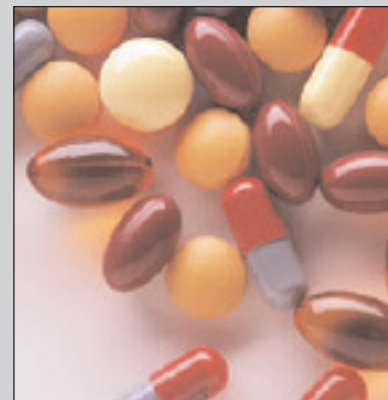
### > EXECUTIVE SUMMARY

Although petrochemicals and electronics have been made through continuous manufacturing for decades, the drug industry is still synonymous with batch manufacturing. However, in recent surveys\* in *Pharmaceutical Manufacturing* magazine, 60% of respondents expect continuous manufacturing to play a greater role in their future, and nearly one third are already running some processes either semicontinuously or continuously.

More-advanced control strategies are also gaining favor. Over 20% of the drug industry professionals who responded to the survey say that they are already applying model predictive control to pharmaceutical processes, while nearly 19% report using advanced control.

However, many drug manufacturers are still hampered by siloed IT and outdated computer and process control technology. And many professionals in the industry, particularly those working in drug scaleup and development, are unhappy with existing IT platforms.

**Pharmaceutical**  
MANUFACTURING



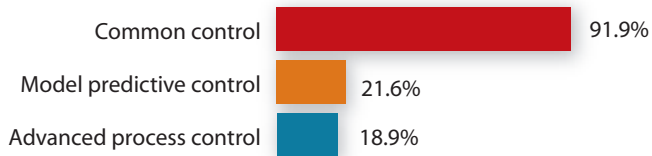
### > KEY FINDINGS

Here are some key findings from the survey:

- Overall, and particularly outside of biopharma, the drug industry's process control strategies are dated and lag well behind those used by other U.S. based manufacturing sectors.
- At most drug manufacturing facilities today, information is still largely siloed and documentation is still handled mainly in paper format.
- Most drug manufacturers are not applying Open Control standards, ISA/ANSI 95 or 88.
- A growing number of drug manufacturers are applying process analytical technologies (PAT), as a bridge to more advanced process control.

# The industry's process control strategies are outdated

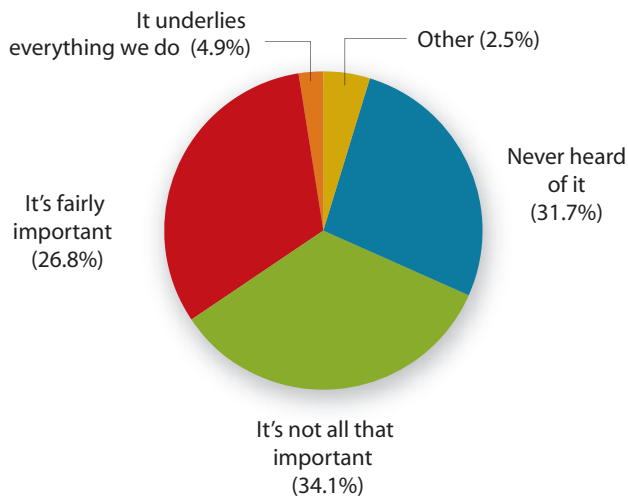
## > USE OF PROCESS CONTROL



## > USE OF OPEN CONTROL

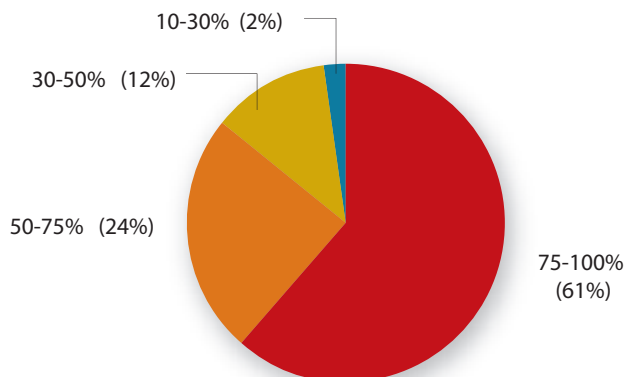
ANSI/ISA 95 and 88 are only being applied by a handful of companies.

## > AWARENESS OF ANSI/ISA 95



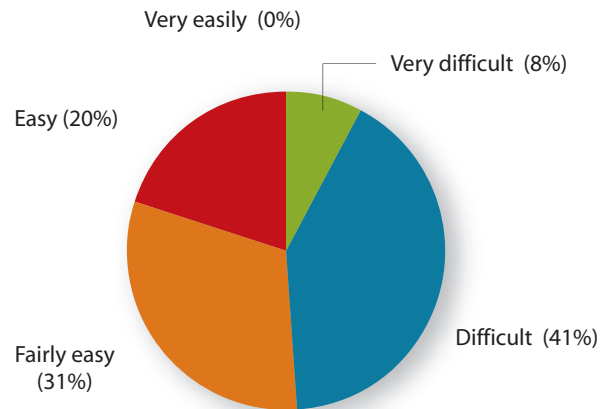
## > PROCESSES ARE STILL PAPER-BASED

Percent of documentation handled on paper



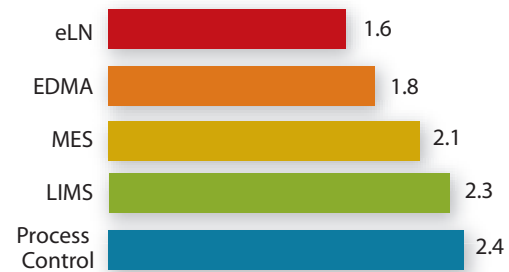
## > DATA ARE SILOED

Data retrieval (outside of usual work scope)



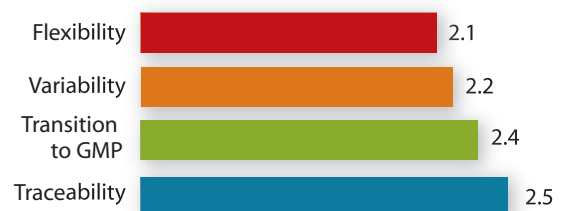
## > READERS ARE DISSATISFIED WITH EXISTING IT

User satisfaction with IT systems (on a scale from 1 to 4 (highest))



## > USER RATING OF IT SYSTEMS CAPABILITIES

(on a scale from 1 to 4 (highest))



## But they want to do more

### > IT AND CONTROL SYSTEMS GOALS

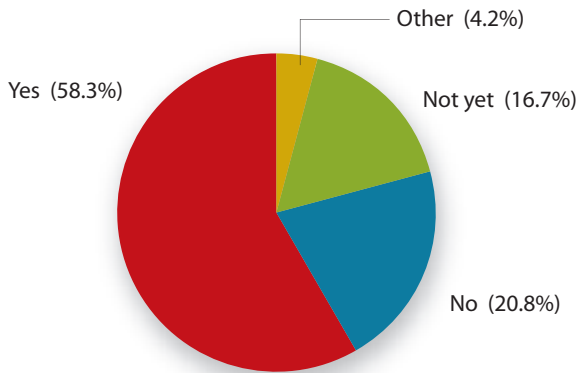
Respondents rated the following Pharma IT and control systems goals as extremely or very important\*

Develop trending for equipment and batch manufacturing	67%
Improve data quality	52%
Move to paperless batch recordkeeping	47%
Integrate time series and other databases	52%
Improve alarm management	45%
Integrate manufacturing floor and ERP	45%
Integrate field sensors to plant floor	46%

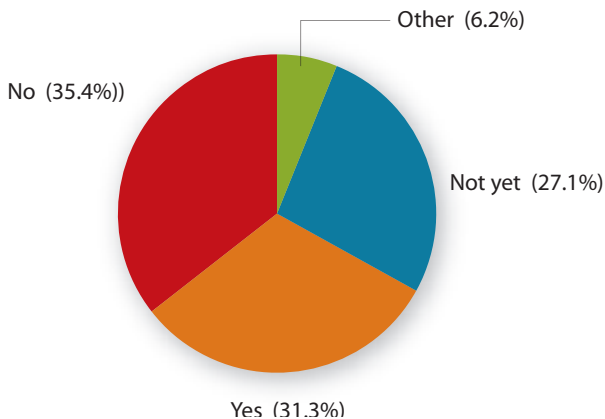
\* Over 20% of the drug industry professionals surveyed by *Pharmaceutical Manufacturing*

## More of them are investing in ERP and MES

### > ARE YOU USING ERP?

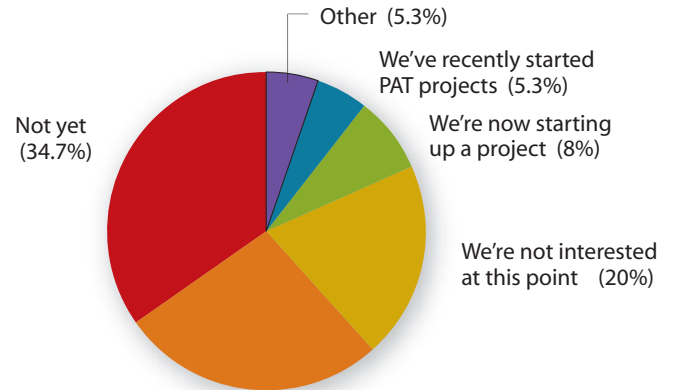


### > ARE YOU USING MES

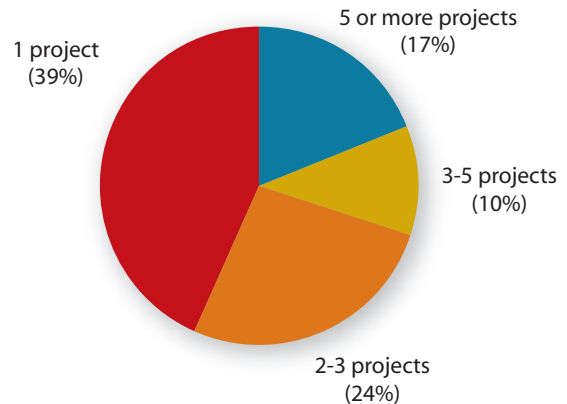


## More of them are working with PAT

### > ARE YOU USING PAT?



### > NUMBER OF PAT PROJECTS UNDER WAY



**Pharmaceutical**  
MANUFACTURING

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### > \*SOURCES

IT and Data Management Survey, *Pharmaceutical Manufacturing*, Nov/Dec., 2005

Process Control Survey, *Pharmaceutical Manufacturing*, June, 2006

Both surveys addressed key questions to a cross section of *Pharmaceutical Manufacturing* readers representing large to smaller pharmaceutical manufacturers.